



# LIMPOPO

PROVINCIAL GOVERNMENT  
REPUBLIC OF SOUTH AFRICA

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OFFICE OF  
**THE PREMIER**

**LIMPOPO PROVINCIAL RESEARCH ETHICS COMMITTEE (LPREC)**

**STANDARD OPERATING PROCEDURES (SOPs)**

## **1. INTRODUCTION AND BACKGROUND**

The Limpopo Provincial Government has identified a need to develop the Provincial Research Guidelines. The Provincial Research Guidelines have been developed with an aim to direct and guide Departments, Parastatals, other stakeholders as well as National Departments in the province to conduct research that is credible, useful, responsive, valid and reliable. The research guidelines serve as a system put in place by the Limpopo Provincial Government to ensure common research approaches in the province at large. The research guidelines put emphasis on the significance of research as a tool used to respond to the needs of the Limpopo community at large. It shall be through the implementation of the research guidelines that communities are to be recognized as focal points of research. This will ensure that research is responsive to their needs and challenges. Therefore, the objectives of the Provincial Research Guidelines are:

- I. To establish standardized and uniform research management systems, procedures, processes in the province;
- II. To promote common research approaches and understanding among departments and researchers in the province;
- III. To assist researchers to conduct research that is accurate, valid, reliable, and responsive to the needs of the province;
- IV. To develop research capacity in provincial departments and municipalities;
- V. To instil the culture of research and usage of research within the public sector;
- VI. To coordinate and manage research activities in the province;
- VII. To recommend provincial departments to adopt and adhere to the Provincial research guidelines and to also comply with them within the scope of their departments; and

It is within this context that the Limpopo Provincial Government has endorsed and approved the Provincial Research Guidelines as a guiding document that will regulate research practices in the province.

The purpose of the Standard Operating Procedures (SOPs) is to clearly articulate the manner in which the Limpopo Provincial Research Ethics Committee (LPREC) operates in as well as promoting the culture of ethical practice when conducting research in the province and ensuring that quality and consistency when reviewing research proposals.

## **2. ESTABLISHMENT OF LIMPOPO PROVINCIAL RESEARCH ETHICS COMMITTEES (LPREC)**

The primary existence of LPREC is to assist the Provincial Government to manage and coordinate research activities in the Province. Moreover, the committee aims to safeguard the rights, dignity and well being of prospective participants.

### **2.1. LPREC Membership**

Head of institutions are requested in writing for nominations of officials to serve in the committee and the Director General of the Provincial Government shall appoint members of the committee through a formal appointment letter which stipulates the term

of office and an assurance that the Office of the Premier will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as committee members.

All members shall be trained on research ethics and principles, and a documented proof of research ethics training shall be produced as a mode of verification.

## **2.2. Compensation of Members**

The Limpopo Provincial Government shall not remunerate members who serve in LPREC; services provided shall be on pro-bono. However, it is acknowledged and appreciated that their service on LPREC requires a significant investment of time.

## **2.3. Roles and Responsibilities of Provincial Research Ethics Committee are to:**

- I. Review all research protocols/proposals;
- II. Approve all research protocols that involve human participants.
- III. Promote and monitor good ethical practice in the province;
- IV. Protect the rights and welfare of research participants;
- V. Approve, reject, and require amendments to a research proposal on ethical and criteria approval grounds;
- VI. Disseminate information on research ethics issues; and
- VII. Audit the activities of research projects to ensure their compliance with research ethics.

## **2.4. Committees' Term of Office**

The term of office of the research ethics committee shall be 3 years. At the elapse of the committees' term of office the institutions will be requested to nominate persons to serve on the committee for the next cycle of term of office. Institutions are at liberty to decide who represents them.

## **2.5. Chairpersonship**

- I. The chairperson and deputy chairperson of the LPREC shall be elected by members of the committees.
- II. The chairperson is appointed from the membership of the LPREC

## **2.6. Powers of Chairperson**

- I. Responsible and accountable for the final approval of the proposals.
- II. Suggest experts for reviewing of specific research proposals.
- III. May co-opt any member to perform certain duties of the committees.
- IV. Represent the views of the committee and Province at large at meetings in government sectors, research and academic institutions.

## **2.7. Composition of Provincial Research Ethics Committee**

- I. Chairperson (an objective person);
- II. Deputy Chairperson;

- III. A community representative (e.g. representative from traditional health practitioner, faith based organisation representative, Community Development Worker Ward, Councillor);
- IV. Members with the knowledge of current experience in the research area;
- V. A member with knowledge of professional care, counselling and treatment of people (i.e. medical doctor, nurse, social worker and psychologist);
- VI. A member who has professional training in both qualitative and quantitative research methodologies;
- VII. Research Directors from universities in the Province (or any other representative nominated by the universities in the province);
- VIII. A statistician;
- IX. A Local Government representative, preferably SALGA;
- X. A legal advisor; and
- XI. Office of the Premier Research Unit (Secretariat and coordinator).

### 3. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST AND CONFIDENTIALITY

- I. Researchers / supervisors and **members of LPREC** must ensure disclosure of affiliation with, or financial involvement in any organization or entity with a direct interest in the subject matter of materials of the project.
- II. LPREC members shall sign confidentiality forms on the first meeting of their term in office and will sign declaration forms every time the committee sits.
- III. Should there be any member with declaration of conflict of interests in any proposal/protocols the member shall recuse him/herself from a meeting, until decisions are made on that particular proposal/protocol.
- IV. These disclosure must cover the full range of potential interests;
  - such as direct benefits like the provision of materials or facilities, and
  - financial or in-kind support; for example payment of travel, accommodation expenses to attend conferences.
- IV. Such disclosure should cover any situation in which the conflict of interest may, or may be perceived to, affect decisions regarding other people.
- V. Researchers / supervisors have an obligation, at the time of reporting, proposing research, or seeking approval from LPREC or other regulatory authorities to declare any conflict or interest which has a potential to influence the project and its conduct.
- VI. Members of LPREC must withdraw from the committee when discussion of projects in which they are personally involved takes place, and must not use their membership to gain a favourable advantage.

### 4. PROPOSALS/PROTOCOLS TO BE REVIEWED BY LPREC

All research that includes human participants and genetic modification of organisms or that has an impact on people must be submitted for review to LPREC, *prior to* commencement of such research projects.

The research proposals/protocols shall be reviewed in accordance with a standardised research proposal template/format provided for in the Provincial Research Guidelines (Check Annexure E).

## **5. APPLICATION FOR ETHICS REVIEW**

Research proposals/protocols shall be submitted electronically to the secretariat of the committee. Application forms and templates are electronically obtainable on the website: <http://policyresearch.limpopo.gov.za/> . Researchers will be encouraged to use this facility in order to get these documents. Attached to the proposal should be the following:

- I. a completed application form (obtainable from the secretariat);
- II. data collection tool;
- III. informed consent form;
- IV. information sheet;
- V. a letter from the university signed by the research supervisor/promoter and the Head of Department: this is in cases where research projects are for academic purposes;
- VI. An ethical clearance certificate/letter from the university if the university has an ethical committee.
- VII. Monitoring schedules and responsible persons and their contact details for clinical trials protocols and studies involving moderate increase over minimal risks; and
- VIII. Disclose conflict of interest, financial interests and information that may result in perception of conflict of interest.

## **6. RESEARCH PROPOSALS/PROTOCOLS REVIEW PROCESS**

Subsequent to the application for ethical review, the secretariat shall pre-review the proposal and check if all necessary documentations are attached this shall be done using a standardised checklist to ensure that the application forms and proposals adhered to standards requirements of the committee.

In the event that forms are not fully completed and proposals having deficiencies the secretariat shall advise researchers accordingly in writing.

Only applications which have successfully passed the secretariat's pre-review stage will be further processed into being pre-reviewed by the committee prior to the sitting of the full committee meeting.

Should there be a proposal that requires specialised expertise and committee members do not possess such, this shall require specialised skills then a specialist/expert will be sought to be part of that particular review.

### **6.1. Reviews at a Full Committee Meeting**

The chairperson shall lead the review process and should the chairperson be unavailable, the deputy chairperson shall assume responsibilities of the chairperson. In the absence of both the chairperson and deputy chairperson, members of the committee shall elect one LPREC member to lead the review process. Whoever is leading the meeting shall be the person signing off minutes and decisions of the meeting together with the secretariat.

Should there be a need to have researchers presenting their proposals in order to clarify some of the queries that may arise during the pre-review and/or review stage then the researcher shall be invited to the meeting.

After offering clarifications the researcher / supervisor shall be excused from the meeting to allow the committee to make decisions regarding the proposal.

Committee members should focus an extensive attention on study design and ethical issues, as these two elements can determine whether a protocol is scientifically sound or not.

## **6.2. Expedited Review**

Research proposals/protocols that may require an expedited review maybe afforded an expedited review only if they have satisfied all requirements in accordance with the research template and checklist.

The total process from submission to approval for major events such as protests and political violence shall take approximately 2 weeks. Whereas, major events such as outbreaks of deadly diseases, floods and other natural disasters shall be approved within 1 to 2 days.

## **6.3. Retrospective Review**

Notably, the LPREC shall not provide a retrospective review such as when a researcher conducts a study without getting ethical clearance and requires ethical clearance after conducting their study.

## **6.4. Review Of Proposals by another REC**

Should LPREC be unable to review proposals/protocols due to time constraints or any other reason beyond control, then the researchers may be advised to seek ethical clearance from other RECs. This option should only be explored when the secretariat and chairpersons have perused the proposals and satisfied themselves that the researcher has adhered to requirements of the LPREC. The decision to direct researcher to approach other RECs should be guided by the following conditions:

- That research ethics committee must be registered with the National Health Research

Ethics Committee (NHREC);

- Subsequent to the attainment of the ethical clearance the researchers must provide a copy of the ethical clearance certificate to LPREC and the relevant department prior to commencing with the project in the Limpopo Province, this should be done within 7 days of the approval date. The relevant department will then provide the researcher with a permission letter to use their facilities in the province; and

- The ethical clearance certificate must indicate the NHREC registration number.

## **7. RECORD KEEPING AND COMMUNICATION OF DECISION**

LPREC shall keep written records of all protocols received for review; this includes proposals, information sheets, informed consent forms, correspondences, approval and rejection letters, ethical clearance certificates, minutes and any other necessary record.

Decisions, which may be approval, revision of the protocol or rejection, shall be recorded in minutes. Specific suggestions for modifications and reasons for rejection shall be given. The outcomes of the review shall be communicated to the investigators by the Secretariat within 10 working days after LPREC meetings.

## **8. FREQUENCY OF MEETINGS, PREPARATION OF AGENDA, REGISTERS OF MEETINGS**

The committees shall hold meetings on a quarterly basis or as and when it is necessary to meet. The quorum of the meeting shall be 33% of the total number of committee members.

The secretariat shall do the following:

- I. Issue invitations of the meetings;
- II. Ensure that members of the committees notify the office if they are not able to attend the meeting;
- III. Ensure that members of the committees receive research proposals/protocols to be reviewed within 10 working days of the scheduled meeting to ensure massive participation and effectiveness during the meeting;
- IV. Record minutes of the meetings and disseminate to members of the committees within 10 working days; and
- V. The chairpersons of the committees may convene meetings on an ad hoc basis depending on the urgency of the matters.

## **9. INFORMED CONSENT**

The consent form and any information given to the participants must clearly provide full contact details of LPREC secretariat who they can contact in the event of problems and complaints.

The committee has developed a standard template on informed consent form and information sheet to guide researchers, please refer to Annexure C.

## **10. TRANSLATIONS**

The LPREC shall ensure that researchers accommodate participants that cannot understand and comprehend the language used in the information materials such as proposals and data collection tools by translating all necessary documents in a language that is easily understood by the participant. The enumerators must also be able to speak and understand the language used by participants.

If translators will be used then information materials should state that privacy will be compromised to that extent. A translator should not influence potential participants unduly during the interpretation process

## **11. SUSPENSION OR DISCONTINUATION OF PROJECTS**

In circumstances where in the approved project is non-compliant with the approved protocol and interest of participants are at risk of harm, LPREC may withdraw approval after following due processes.

The LPREC shall inform the researcher and other interested parties in writing on the decision to suspend the projects and state reasons.

## **12. HANDLING OF COMPLAINTS**

Handling of minor complaints from researchers shall be done through the secretariat and the chairperson. Complaints shall be received in writing and response of such complaints will be done in writing as well.

Major complaints shall be submitted in writing to the secretariat or chairperson and such complaints will be tabled for discussions in the committee meeting and the committee will respond to the complainant in writing.

The committee will make efforts to address complaints as presented to them should the complainant be unsatisfied with response the NHREC shall be approached to adjudicate the complaints.

## **13. COMPLIANCE REPORTING TO THE NHREC**

LPREC shall submit report to NHREC on an annual basis or as and when required and make sure all the necessary records are available for inspections, assessments and audit.

## **14. REPORTING ON SERIOUS AND UNEXPECTED ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS**

Research approved by LPREC, Serious and Unexpected Adverse Events (SUSARS, Serious Adverse Events (SAEs) and Adverse Events (AEs) must be reported to the REC secretariat at [mokobij@premier.limpopo.gov.za](mailto:mokobij@premier.limpopo.gov.za) within 7 days or as soon as possible after the occurrence of the event. Researchers may contact the REC chairs directly for advice on [thembinkosi.mabila@ul.ac.za](mailto:thembinkosi.mabila@ul.ac.za) that may impact on the current and future safety of research participants. Such events may range from death through injury to emotional, social and dignitary harms arising from study participation. These reports will be reviewed by LPREC and a written feedback will be given to the researcher/investigator on each occurrence. The LPREC may, *inter alia*, require remedial actions, future preventative actions, amendment to the study or closure of the study.

## **15. SAFETY MONITORING AND PROGRESS REPORT**

In accordance with ethics legislations, LPREC shall monitor adherence of the approved proposals/protocols to minimise risks and protect participants. The frequency and type of monitoring will be in accordance with the degree of anticipated risks to participants.

The LPREC monitoring process will be done as follows:

- Through quarterly reporting from departments and annual reporting from independent researchers. This will provide LPREC with information on how the approved research projects have/are progressing from the time of approval to the completion of those projects.



- Departments will be required to submit these quarter progress reports to keep the committee abreast on the research protocols/proposals. Independent researchers will also be required to do the same.

Lines of communication between LPREC and the applicant will be clearly specified in the communication of the review result of the applicant to outline how monitoring will be conducted

The following will be outlined on the clearance certificate:

- Ethically approved studies must apply for renewal annually
- Ethics approval will not be valid when an annual renewal is not granted by LPREC
- Applications for annual renewal must be made a month before expiry date stipulated on the clearance certificate.

#### **i. Active Monitoring**

The committee will form sub-committees which will be tasked to undertake active monitoring of research projects. The committee will sample research projects that need to be monitored and assign such sampled projects to the sub-committee to undertake monitoring of approved and ethically approved research projects.

#### **The follow-up procedure will take the following into consideration:**

- The requirements laid down for follow-up reviews, the reviews, and the communication procedure. This may vary from the requirements and procedure for the initial decision on an application.
- The follow-up review intervals are determined by the nature and events expected in relation to particular research projects, though each research project should undergo a follow-up review at least once a year.

#### **Events leading to indications for a follow-up review of a study**

Indications that will make LPREC decide to make a follow up or monitoring visits of a project includes:

- Any protocol likely to affect the right, safety, and /or well-being of the research participants or the conduct of the study
- Serious and unexpected adverse event related to the conduct of the study or study results, and the response taken by investigators, sponsors, and regulatory agencies, when applicable
- Any event or new information that may affect the benefit/risk ratio of the study
- A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the LPREC's original decision or confirmation that the decision is still valid

#### **NOTE:**

In the case of the premature suspension/ termination of a research project that was approved by LPREC, the applicant should notify the LPREC immediately of the suspension/ termination.

### Outcome of the review

- A summary of results obtained in a study prematurely suspended/terminated should be communicated immediately to LPREC

### ii. Active Monitoring Tool

Below is the tool to be used when committee undertakes the active monitoring exercises.

Research Project Title	Stage/Phase	Activities Involved	Start Date of the Project	Estimated Completion Date of the Project	Progress (Deliverables)	Recorded SAEs	SAEs Mitigations	Challenges/Comments

## 16. RESEARCH APPROVAL TEMPLATE AND CHECKLIST FOR RESEARCHERS

The checklist will serve as a guideline for researchers and it will be provided to researchers when applications are made (refer to item 5). This checklist will comprise of all the requirements needed for the proposal/protocol to be approved. The system of providing researchers with the checklist will assist researchers to ensure that the research proposal/protocols are aligned to the requirements of the LPREC (See Annexure B).

## 17. ETHICAL APPROVAL AND CLEARANCE CERTIFICATE

Under the terms and conditions in the approval letters, it shall be stated that a researcher must immediately report anything that might warrant review of ethical approval of the proposal/protocol, including:

- I. Serious or unexpected adverse effects;
- II. Propose changes in protocol;
- III. Unforeseen events that might affect continued ethical acceptability of the project.

The ethical clearance certificate shall stipulate the following:

- I. In case of non-compliance, the researcher will be subjected to the certificate being withdrawn by the committee;
- II. The certificate will be valid for a period of 12 months;
- III. If the researcher hasn't collected data within that period, then the certificate will be considered as null and void and will have to be renewed through the ethics committee.

## 18. INDUCTION, ORIENTATION AND TRAINING OF MEMBERS

The following should be taken into consideration:

- I. At the beginning of a new member's term, before a member participates in LPREC activities, induction, orientation or training shall be provided:
  - II. The ethicist and research methodologist shall present a brief overview of the principles of ethics, morals and research.
  - III. The secretariat will make available the TORs, SOPs, and guidelines documents and explain the administrative procedures which a member must be familiar with.
  - IV. The chairpersons will introduce the member to the responsibilities, functions, procedural matters and operations of LPREC and what is expected of members.
  - V. All members will be required to attend at least one ethics training workshop arranged by Office of the Premier.
  - VI. LPREC will endeavour to keep members up to date on any new developments on a regular basis by regularly making available any new information, inviting experts to address LPREC.
  - VII. LPREC will endeavour to develop and update a dedicated website containing all relevant ethics documents and information.
- In light of the above, LPREC secretariat and chairpersons will encourage members to register for research ethics online courses and also ensure that they arrange training offered by credible institutions.

## **19. MONITORING AND EVALUATION OF APPROVED RESEARCH**

The LPREC, Office of the Premier and responsible departments shall ensure that approved research projects are monitored and evaluated. This process will ensure that objectives as stipulated in the proposal are achievable in cases of on-going research projects and also if the objectives have been achieved in cases of completed research projects. It is of vital importance to assess if the projects are responsive to their desired goals. The researchers shall also provide progress made to the committees and the Office of the Premier.

## ANNEXURE A: RISK LEVEL DESCRIPTORS

### RISK LEVELS FOR HEALTH AND HEALTH RELATED RESEARCH

Within the context of LPREC, a risk is defined as probability of harm occurring to a participant as a result of participation in a research” (Department of Health. Second Edition. Ethics in Health Research. Principles, Processes and Structures, 2015). Additionally, Harm is considered to be anything that has a negative effect on participant’s welfare (Department of Health. Second Edition. Ethics in Health Research. Principles, Processes and Structures, 2015). Below is the classification of risks levels for health projects:

Risk Category	Definition	Explanations and /or Examples
<b>No risk</b>	No contact with human participants	For instance these studies could be systematic reviews or reviews of literature available in the public domain and theoretical frameworks.
<b>Minimal, low or negligible risk</b>	<p>The probability, magnitude or seriousness of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life (“daily life” as a benchmark should be the daily experience of an average person</p> <p>Research in which the only foreseeable risk is one of the minimal discomfort or inconvenience.</p>	<p>This may include:</p> <p><b>Market research surveys,</b> investigations of <b>largely uncontroversial topics</b> undertaken through interviews, surveys and participant observations, <b>research on insensitive issues</b> such as opinions than personal information, <b>interviews with officials and practitioners</b> in their official capacity, <b>document analysis,</b> <b>bio-physical research</b> involving previously collected or collection of human blood through sputum or urine, <b>commercially available cell line research</b> where cells are not infected or undergo genetic modification, <b>participants are adults</b> and not considered to be a vulnerable research population, <b>use of anonymised</b> data from medical schemes databases, focus groups with potential of <b>loss of anonymity but not on a sensitive subject,</b> and <b>Review of privileged</b></p>

		<b>literature/documentations</b> such as privileged records of a company's annual meetings with a low level of sensitivity.
<b>Medium risk (above minimal risk)</b>	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.	One or more of the following may apply: <ul style="list-style-type: none"> <li>• The risk of harm is reasonable in relation to the anticipated benefit;</li> <li>• The risk of harm is reasonable in relation to the importance of the anticipated knowledge gained;</li> <li>• The risk of harm includes several identified risks;</li> <li>• The research topic is considered sensitive</li> <li>• Information gathered is personal, rather than opinions or attitudes;</li> <li>• Involves face to face contact with participants through:             <ul style="list-style-type: none"> <li>-interviews dealing with personal sensitive information or within a power differential</li> <li>- focus groups with potential of loss of anonymity and sensitivity</li> </ul> </li> <li>• Psychosocial intervention studies;</li> <li>• The intervention can cause physical, psychological or social harm;</li> <li>• Research involving</li> </ul>

		<p>collection of more than human blood through needle prick, sputum or urine samples e.g venepuncture;</p> <ul style="list-style-type: none"> <li>• Commercially available cell line research where cells are infected or undergo genetic modification;</li> <li>• The information needs to be collected with personal identifiers (e.g id numbers, identifier name, student numbers etc);</li> <li>• The research participants may come from vulnerable or marginalized group, such as those involved in dependent relationships with disabilities, people living with HIV or other chronic disease, the economically disadvantaged</li> <li>• Use of patient information in existing health systems; and</li> <li>• Use of laboratory test of patients in existing health systems</li> </ul>
<b>High Risk</b>	Research in which there is a real and foreseeable risk of harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner	<p>One or more of the following apply:</p> <p>The intervention can cause serious physical or psychological adverse consequences;</p> <p>Pharmaceutical drug research;</p>

		<p>Research involving highly sensitive topics and/or very vulnerable and marginalized communities e.g. people with multiple vulnerabilities;</p> <p>Research involving the deception of the participants who are illegal immigrants or engaged in illegal activities;</p> <p>Collection of biological samples through invasive techniques e.g. surgery;</p> <p>By agreeing to participate in the research participants will be placed at a real risk of harm;</p> <p>The researcher (or research team) will be placed at a real risk of harm;</p> <p>The researcher may be placed at a risk of breaking the law by carrying out certain activities, e.g. research investigating gang activities and possession of illegal firearms; and</p> <p>The research may reveal information that requires action on the part of the researcher or an institution (private or public) that could place the participant or others at risk, e.g research involving victims of physical or sexual abuse, victims of domestic violence, etc.</p>
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## 2. RISK LEVELS FOR HUMANITIES AND RELATED FIELDS

Risk Category	Definition	Explanation and/or Examples
<b>No risk</b>	No contact with human participants	Certain systematic reviews; reviews of literature available in the public domain; and theoretical frameworks.
<b>Minimal, low or negligible risk</b>	<p>The probability, magnitude or seriousness of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life (“daily life” as a benchmark should be the daily experience of an average person</p> <p>Research in which the only foreseeable risk is one of the minimal discomfort or inconvenience.</p>	<p>This may include:</p> <p><b>Market research surveys</b>, investigations of <b>largely uncontroversial topics</b> undertaken through interviews, surveys and participant observations, <b>research on insensitive issues</b> such as opinions than personal information, <b>interviews with officials and practitioners</b> in their official capacity, <b>document analysis, participants are adults</b> and not considered to be a vulnerable research population, <b>focus groups</b> with potential of <b>loss of anonymity but not on a sensitive subject</b>, and <b>Review of privileged literature/documentations</b> such as privileged records of a company’s annual meetings with a low level of sensitivity.</p>
<b>Medium risk (above minimal risk)</b>	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.	<p>One or more of the following may apply:</p> <ul style="list-style-type: none"> <li>• The research topic is considered “sensitive”;</li> <li>• Information gathered is personal, rather than opinions or</li> </ul>



		<p>attitudes;</p> <ul style="list-style-type: none"> <li>• The information needs to be collected with personal identifiers (e.g id numbers, identifier name, student numbers etc);</li> <li>• Review of privileged literature/documentation e.g privileged records of a company's annual meetings with a low level of sensitivity;</li> <li>• The research participants may come from a vulnerable or marginalized group, such as those involved in dependent relationships, with disabilities, people living with HIV or other chronic diseases, economically disadvantaged, etc.</li> <li>• Involves face to face contact with participants through: <ul style="list-style-type: none"> <li>-interviews dealing with personal sensitive information or within a power differential</li> <li>- focus groups with potential of loss of anonymity and about sensitive subjects</li> </ul> </li> </ul>
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<b>High Risk</b>	Research in which there is a real and foreseeable risk of harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner	<p>One or more of the following apply:</p> <p>The intervention can cause serious physical, social or psychological adverse consequences;</p> <p>Research involving highly sensitive topics and/or very vulnerable and marginalized communities e.g. people with multiple vulnerabilities;</p> <p>Research involving the deception of the participants</p> <p>Research investigating illegal activities e.g. illegal immigrants or people engaged in illegal activities;</p> <p>By agreeing to participate in the research participants will be placed at a real risk of harm;</p> <p>The researcher (or research team) will be placed at a real risk of harm;</p> <p>The researcher may be placed at a risk of breaking the law by carrying out certain activities, e.g. research investigating gang activities and possession of illegal firearms; and</p> <p>The research may reveal information that requires action on the part of the researcher or an institution (private or public) that could place the participant or others at risk, e.g research involving victims of physical or sexual abuse, victims of domestic violence, etc.</p>
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## **ANNEXURE B: SERIOUS ADVERSE EVENTS FORM**

This form must be completed and returned to the LPREC secretariat, mokobij@premier.limpopo.gov.za as soon as possible but within 7 days for serious adverse events, and within 15 days for other adverse and unexpected events. One form is to be completed per participant, even if several participants are involved in a similar adverse event.

**TITLE OF THE STUDY:**

**BRIEF DESCRIPTION OF THE STUDY:**

**DESCRIPTION OF THE INTERVENTION:**

**LPREC Research Ethics Clearance Number:**

### **1. PARTICIPANT INFORMATION**

Participant ID:

Participant Age:

Participant Gender:

### **2. ADVERSE EVENT**

**2.1. AE REPORT TYPE:** ☐ Initial ☐ Follow-up

**2.2. DATE OF ADVERSE:**

**2.3. ADVERSE EVENT REPORTED TO RESEARCHERS BY:**

☐ Study participant returning to the site

☐ By other means, specify:

### **3. COMPONENT OF STUDY, PARTICIPANT INVOLVED IN:**

1 ☐ Baseline 3 ☐ Six months

2 ☐ Six Weeks 4 ☐ Other, Specify

### **4. ADVERSE EVENT SEVERITY**

1. ☐ Mild 3 ☐ Severe

2. ☐ Moderate 4 ☐ Fatal

**5. ADVERSE EVENT DESCRIPTION:**

**6. IS THE ADVERSE EVENT SERIOUS?** ☐ 1. Yes ☐ 2. No

**SERIOUS ADVERSE EVENTS ARE CONSIDERED FATAL OR LIFE THREATENING THAT REQUIRE HOSPITALIZATION OR PROLONG EXISTING HOSPITALIZATION, OR RESULT IN PERSISTENT OR SUGNIFICANT DISABILITY**

**7. CLASSIFICATION OF ADVERSE EVENT**

- ☐ Results
- ☐ Is life-threatening
- ☐ Requires inpatient hospitalization or prolongation of existing hospitalization
- ☐ Results in persistent or significant disability/incapacity
- ☐ Any other experience that suggests a significant hazard, contraindication, side effects, or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above
- ☐ Events changes the risk/benefit ration of the study

**8. AT THE TIME OF THIS REPORT, THE ADVERSE EVENT IS:**

- ☐ Resolved (No additional follow-up necessary)
- ☐ Unresolved (Additional follow-up necessary)

## 9. RESEARCH STAFF ASSESSMENT OF ADVERSE EVENT

**9.1 IN YOUR JUDGEMENT, IS THE ADVERSE EVENT RELATED, POSSIBLE RELATED, UNKNOWN OR NOT RELATED TO THE PROTOCOL?**

- ☐ Related
- ☐ Possibly Related
- ☐ Unknown
- ☐ Not related

## 10. VERIFICATION

STAFF MEMBER:

COMPLETED BY (PLEASE PRINT OR TYPE):

FIRST NAME:

LAST NAME:

DESIGNATION/ROLE ON RESEARCH PROJECT:

STAFF MEMBER SIGNATURE:

DATE:

PRINCIPAL INVESTIGATOR (PLEASE PRINT OR TYPE):

*I have reviewed this AE Form for this participant and attest that the information recorded is accurate and complete.*

INVESTIGATOR'S NAME:

INVESTIGATOR'S LAST NAME:

INVESTIGATOR'S SIGNATURE:

DATE:

## **ANNEXUREC: LPREC GENERIC INFORMATION SHEET AND CONSENT FORM**

### **Introduction of the enumerator**

Identify yourself and the institution you are representing.

### **Brief introduction and background of the study**

Describe the problem that this research project is trying to solve and its intended purpose.

### **What will the study involve?**

Will the participants be requested to provide a blood sample or provide any medical or private and personal information? In the informed consent document, it is important to not deviate too far from the topic of the study with examples to explain certain concepts. But on the other hand, you should seek to make sure all the necessary information is gathered.

### **Your voluntary participation and right to withdrawal**

Request the potential respondent for permission to participate in the study and also indicate the estimated time of the interview.

Explain to the respondent that **participation is voluntary** and not being forced to take part in this study. The choice of whether to participate or not, is the respondent's decision alone. If they choose not to take part, they will not be affected in any way whatsoever. If they agree to participate, they may stop participating in the research at any time and there won't be any penalties or prejudice.

### **Confidentiality and Anonymity**

Explain how confidentiality and anonymity will be upheld during and after the study, thus explain what will happen to the data collected.

Should the enumerator need to tape-record the interview, they should seek permission from the researcher first.

### **Risks/discomforts**

The enumerator must explain any risks and harm that maybe associated with participation in the study should there be any, these risks should be explained and discussed in the informed consent document. Inserting the section on potential risks may prevent the misunderstandings about the project. Some of the risks that may need to be mentioned include the risk to individual such as breach of confidentiality and other physical risks such as risks associated with drawing of blood or non-physical risks such as loss of privacy. There may be other unknown risks to participation that an investigator might want to share with participants. For example, research

results could have the potential under certain circumstances be misconstrued and used to discriminate and/or stigmatize a population.

### **Potential benefits associated with the study**

Are there any immediate or indirect benefits from participating in the study? The consent form must clearly explain what the benefits will be. The researchers should be careful with emphasising more on immediate benefits such as nutritional supplements, food or compensation because this may lead to false inducement. However, the points that the researcher may need to mention on the informed consent are: benefits of the study to the society and likely lack of immediate benefit to participants.

### **How participants will be protected?**

It should be emphasised in the consent form that the identity of the participants will be protected at all times, and that data will be kept secured in locked cabinets in a locked room or in password protected databases.

### **Who to contact if you have been harmed or have any concerns**

This research has been approved by the Limpopo Provincial Research Ethics Committee (LPREC). If there are any complaints about ethical aspects of the research or any feeling that the respondent has been harmed in any way by participating in this study the LPREC secretariat must be contacted on [mokobij@premier Limpopo.gov.za](mailto:mokobij@premier Limpopo.gov.za) or 015 287 6564 or chairperson on [thembinkosi.mabila@ul.ac.za](mailto:thembinkosi.mabila@ul.ac.za) or 015 268 2401.

### **CONSENT: (a consent should be documented with a signature on a separate sheet).**

I hereby agree to participate in research on..... I understand that I am participating freely and without being forced in any way to do so. I also understand that I can stop participating at any point should I not want to continue and that this decision will not in any way affect me negatively. I understand that this is a research project whose purpose is not necessarily to benefit me personally in the immediate or short term. I understand that my participation will remain confidential.

.....

**Signature of participant**

**Date:**.....

**CONSENT FOR TAPE RECORDING** <If applicable.>

I hereby agree to the tape-recording of my participation in the study. <If applicable.>

.....

**Signature of participant**

**Date:**.....

I understand that the information that I provide will be stored electronically and will be used for research purposes now or at a later stage.

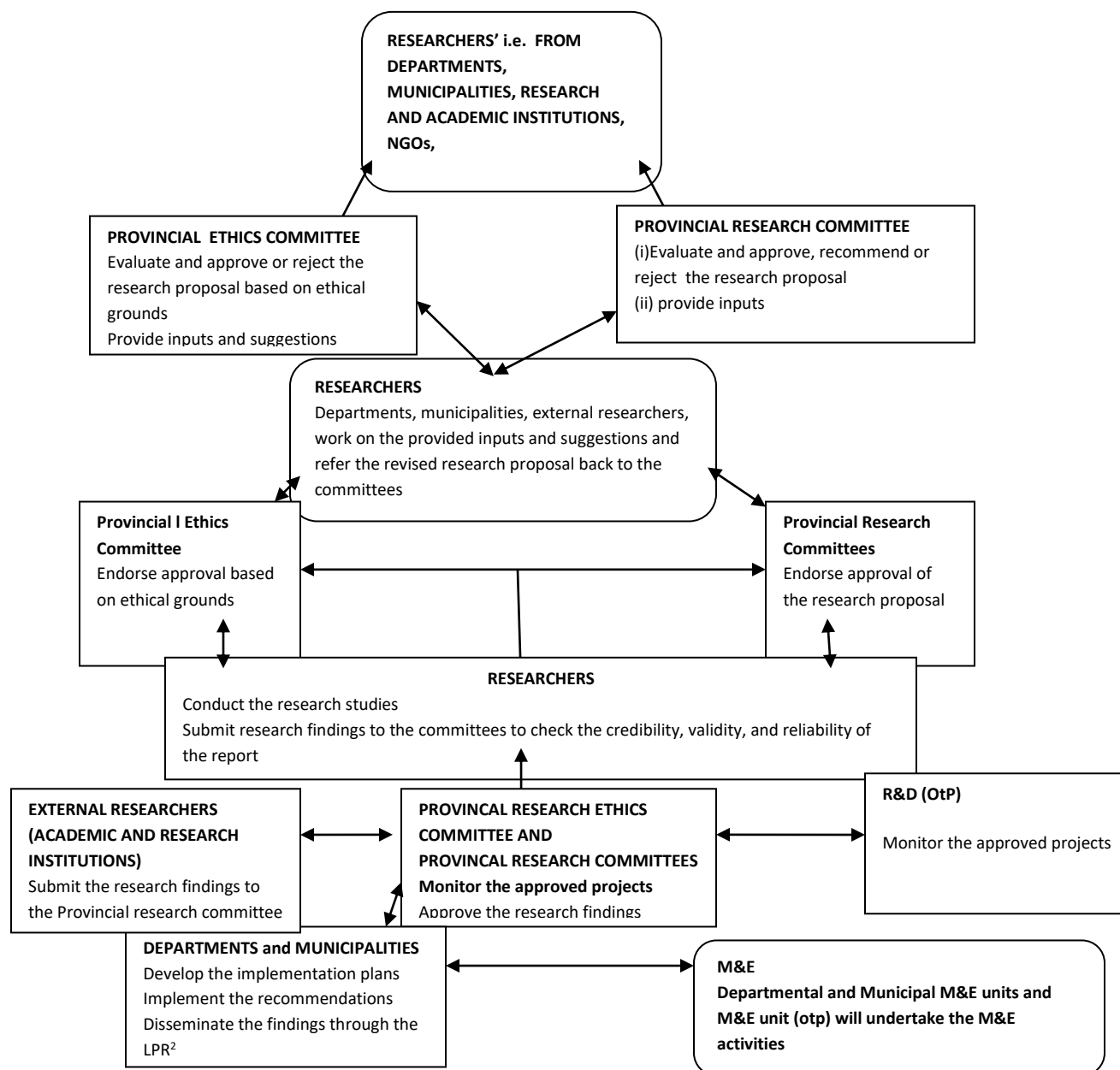
.....

**Signature of participant**

**Date:**.....



## ANNEXURE D: LPREC WORK FLOW



# ANNEXURE E: RESEARCH PROPOSAL EVALUATION FORM

The LPREC shall assess and evaluate the research proposals using the proposed format/criteria below.

<b>Research Title</b>															
	<b>Name of the Institution/Department</b>														
	<b>Address of the Institution/Department</b>														
	<b>Date of Proposal Submission</b>														
	<b>Evaluator's (Chairperson) Details</b>														
	<b>Signature of Evaluator</b>														
	<b>Date of Signature</b>														
<table border="1"> <thead> <tr> <th>Evaluation Areas</th> <th>Yes</th> <th>No</th> <th>Provincial Ethics Comments</th> <th>Research Committee's</th> </tr> </thead> <tbody> <tr> <td> <b>1. Research Relevance</b> <ul style="list-style-type: none"> <li>Is the topic/title of the study well comprehended? Is it a researchable topic?</li> <li>Is the problem statement clearly articulated?</li> <li>Does the proposal address provincial needs, challenges and priorities?</li> </ul> </td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>						Evaluation Areas	Yes	No	Provincial Ethics Comments	Research Committee's	<b>1. Research Relevance</b> <ul style="list-style-type: none"> <li>Is the topic/title of the study well comprehended? Is it a researchable topic?</li> <li>Is the problem statement clearly articulated?</li> <li>Does the proposal address provincial needs, challenges and priorities?</li> </ul>				
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<b>1. Research Relevance</b> <ul style="list-style-type: none"> <li>Is the topic/title of the study well comprehended? Is it a researchable topic?</li> <li>Is the problem statement clearly articulated?</li> <li>Does the proposal address provincial needs, challenges and priorities?</li> </ul>															

	<ul style="list-style-type: none"> <li>Is the research explicit on how it will contribute to provincial needs, challenges and priorities?</li> </ul>				
2.	<b>Research Questions and Objectives</b> <ul style="list-style-type: none"> <li>Are the research questions clear?</li> <li>Is the aim of the proposed study clear?</li> <li>Are objectives of the study clear and measurable?</li> <li></li> </ul>				
3.	<b>Research Methods</b> <ul style="list-style-type: none"> <li>Is the sampling method clearly articulated?</li> <li>Are data collection methods outlined and clear?</li> <li>Is the kind of data to be gathered outlined?</li> <li>Are data analysis techniques clearly articulated?</li> <li>Is the questionnaire for data collection attached?</li> </ul>				
4.	<b>Ethical considerations</b> <ul style="list-style-type: none"> <li>Is anonymity assured?</li> <li>Is privacy and confidentiality assured?</li> <li>Will the study give provision to participants for voluntarily participation?</li> <li>Has the researcher developed and submitted the consent form?</li> <li>Does the consent form give participants sufficient information to decide if they want to partake in the study or not?</li> <li>Does the consent form provide provision for participants to withdraw if they want to?</li> <li>Is the language in the consent form user friendly for participants to</li> </ul>				

	<p>understand?</p> <ul style="list-style-type: none"> <li>Has the researcher determined the social value of the study i.e. the perception and impact of the study to the social realm?</li> </ul>				
	<p><b>Research Outputs and Outcomes</b></p> <ul style="list-style-type: none"> <li>Are expected research outcomes clearly articulated?</li> <li>Are the expected deliverables of the proposed study outlined?</li> </ul>				
	<ul style="list-style-type: none"> <li>Does the research proposal meet South African Statistical Quality and Assessment Framework (SASQAF) requirements?</li> </ul>				
	<p><b>Research Project Management</b></p> <ul style="list-style-type: none"> <li>Are the Timelines clear? (What is the start and finish date?)</li> <li>Is the budget realistic?</li> </ul>				
	<p><b>Language</b></p> <ul style="list-style-type: none"> <li>Is the use of vocabulary appropriate?</li> </ul>				
	<ul style="list-style-type: none"> <li>Is the spelling used correct?</li> </ul>				
	<ul style="list-style-type: none"> <li>Is the proposal well written to avoid ambiguity?</li> </ul>				
	<ul style="list-style-type: none"> <li>Is the letter from language editor attached?</li> </ul>				
	<p><b>Administrative Requirements (Applicable to University studies only)</b></p> <ul style="list-style-type: none"> <li>Did the supervisor and Head of the Department sign off the proposal? (attach the letter from the supervisor and HOD)</li> </ul>				

	<ul style="list-style-type: none"> <li>Did the proposal go through proper approval channels of the university i.e. school and faculty research committees? (attach the letter if available) )</li> </ul>				
	<ul style="list-style-type: none"> <li>Did the proposal go through university ethical clearance processes? (if yes attach the ethical clearance certificate)</li> </ul>				
<b>Research Proposals Recommendations</b>	<ul style="list-style-type: none"> <li>Research proposal accepted without changes(the committee is recommending that the researcher should continue with the project and provide progress reports on a quarterly basis)</li> </ul>				
	<ul style="list-style-type: none"> <li>Research proposal is accepted with conditions and minor comments/changes (the researcher should work on the comments and resubmit to the committees)</li> </ul>				
	<ul style="list-style-type: none"> <li>Research proposal accepted with major changes(the researcher should work on the comments and resubmit to the committees)</li> </ul>				
	<ul style="list-style-type: none"> <li>Research proposal rejected (the researcher should work on the comments and resubmit to the committees)</li> </ul>				

## ANNEXURE F: RESEARCH ETHICS CLEARANCE CERTIFICATE



**LIMPOPO**  
PROVINCIAL GOVERNMENT  
REPUBLIC OF SOUTH AFRICA

### OFFICE OF THE PREMIER

Office of the Premier

Research and Development Directorate

Private Bag X9483, Polokwane, 0700, South Africa

Tel: (015) 287 6564, Email: mokobij@premier.limpopo.gov.za

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### LIMPOPO PROVINCIAL RESEARCH ETHICS COMMITTEE (LPREC) CLEARANCE CERTIFICATE

**Meeting Date:**

**Project Number: (for example LPREC/16/2018: PG)**

**Title of the Study:**

**Researcher:**

**Department/Institution:**

Signature of the Chairperson: Limpopo Provincial Research Ethics Committee

LPREC's National Health Research Council (NHREC) Registration Number

**Note:**

- i. This study is categorized as a Low Risk Level in accordance with risk level descriptors as enshrined in LPREC Standard Operating Procedures (SOPs)
- ii. Should there be any amendment to the approved research proposal; the researcher(s) must re-submit the proposal to the ethics committee for review prior data collection.
- iii. The researcher(s) must provide annual reporting to the committee as well as the relevant department.
- iv. The ethical clearance certificate is valid for 12 months. Should the need to extend the period for data collection arise then the researcher should renew the certificate through LPREC secretariat

**PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRIES**